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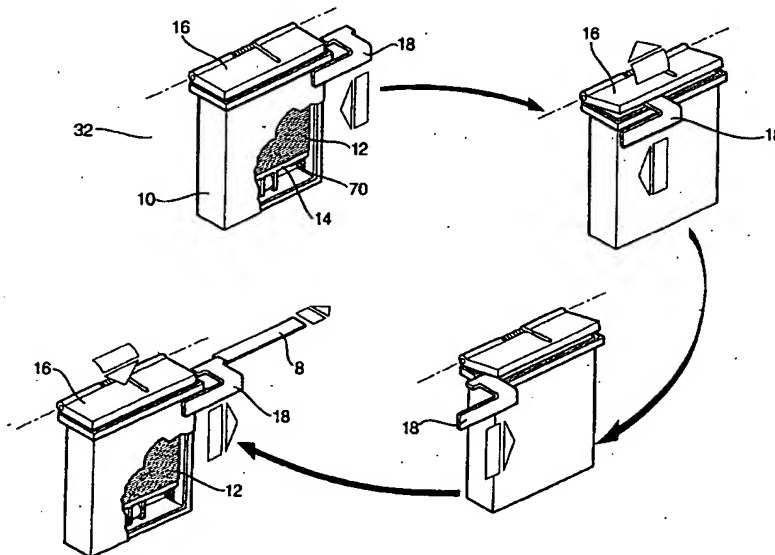
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(54) Title: SENSOR DISPENSING DEVICE



(57) Abstract: An embodiment of a sensor dispensing device for dispensing sensors for measuring analyte concentration in a fluid includes a cartridge assembly (32) having a housing (70) with an opening and means (16) for making a moisture-proof seal around the opening. A stack of sensors (12) is stored in the housing (70) and urged through the opening towards a stop member (73) by spring means. The device is provided with an externally actuatable pusher (18) for breaking the seal and for pushing a single sensor from the housing.

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strip. Test devices are known in which a plurality of test strip are provided on a cartridge disc. Each strip is housed in its own sensor slot, and means are provided to eject a test strip from its slot when required, and to automatically locate it in a sensor holder. Examples of test devices with test strip dispensers are described in US Patent No. 5,660,791, and European Patent Application Numbers 0 732 590, 0 738 666, and 0 811 843.

10 A problem with test strips is that they have only a limited shelf life, and exposure of test strips to the atmosphere further reduces the shelf life.

It has been proposed in WO 94/10558 to provide a stack of disposable sensors in a cylindrical housing, the stack being urged towards a test station to form a liquid-proof seal. In DE 196 39 226 A1 it is proposed to provide a test device with a cartridge that may have a plurality of chambers containing test strips, each of which chambers may be individually sealed to preserve the shelf life of the strips therein. A user removes the seal for each chamber when required, and a timing circuit may be activated either by the user or when the cartridge is pushed into the device. After a set time period has elapsed, an alarm or other indication reminds the user that the time period for using the strips has elapsed.

It is an object of the present invention to provide an improved test device. It is a further object of the invention to provide an improved dispenser for sensors for use in measuring analyte concentration in an applied fluid.

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preferred embodiment, however, the device further comprises signal-reading means for determining the concentration of an analyte in an applied sample according to a signal generated by the sensor in the dispensed position. The signal-reading means may comprise electronic circuitry for measuring an electric signal generated by the sensor in response to analyte concentration in an applied sample. With the sensor in the dispensed position its electrodes engage with contacts connected to the circuitry, in known manner. Alternatively, the signal-reading means may measure an optical change in the sensor, for example a colour change. Many suitable signal-reading means are known to those skilled in the art.

By providing the stop member on the housing or on a support around the housing the sensors may be provided in a pre-assembled cartridge which can be inserted into the dispenser or into a test device and be ready for use without further user actions.

20

The stop member may be a wall of the housing so that the housing comprises a box which is closed save for a fixed gap on one wall through which the sensors are pushed, and a gap through which the pushing member is disposed when pushing a sensor. Alternatively the stop member could extend across only a part of the opening, sufficient to prevent sensors from being urged out of the housing by the spring means. In this case, there may be a single gap which extends along one wall of the housing.

30

The gap could be dimensioned to permit a plurality of sensors to be pushed simultaneously from the housing;

The externally actuatable means are preferably actuated mechanically by a user moving an external actuator, for example a movable sleeve or handle on the dispenser or
5 test device. Additionally, or alternatively, actuation may involve one or more electric or other motorised means; for example a user may press a button which operates a motor.

- 10 The movement of the pushing member may be in the same direction as that of the external sleeve or handle, or it may be at an angle, notably perpendicular to the direction of movement of the external actuator, by means of a series of linkages which convert translational motion to
15 rotational motion and vice versa.

In a preferred embodiment, adjustment of the cap to the open position and movement of the pushing member are actuated by adjustment of a single external actuator. It
20 is particularly preferred that the pushing member itself acts to adjust the cap to the open position. The pushing member may be a slider which from an initial rest position slides so as to insert itself between the cap and the housing, thereby adjusting the cap to the open position,
25 and which subsequently pushes a sensor from the stack to the engagement location. Preferably the arrangement is such that the pushing member undergoes reciprocal movement.

- 30 The invention will be described with reference to the testing of glucose concentrations in blood, but it will be understood that the invention is not limited to this

In a preferred embodiment the sealing surface is provided by a support member in which the housing is received. In this embodiment, the housing comprises a cartridge inner member and the support member comprises a cartridge outer member.

The cartridge inner member may be sold and dealt in separately, so that the cartridge outer is retained and only the inner member replaced when necessary.

10 Accordingly, a further aspect of the invention provides a cartridge inner member comprising:

a) a housing having a plurality of sensors arranged in a stack therein, each sensor carrying reagent means for producing a signal in response to the concentration of analyte in an applied fluid;

b) the housing having an opening of sufficient dimensions to permit a sensor to pass through the opening;

c) a stop member located beyond the opening which limits outward travel of sensors from the stack;

20 d) a spring means which urges the sensors towards and into contact with the stop member;

e) a fixed gap between the stop member and the said opening of suitable dimensions to permit a sensor to be pushed through the said gap;

25 wherein the opening of the housing has two opposed long edges and two opposed short edges, the stop member being attached to or integrally formed with one of the said long edges, and the said gap being laterally accessible through a channel disposed substantially parallel to and extending along the entire length of the other of the said long edges.

30

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be further described, by way of example, with reference to the following drawings in
5 which:

Figure 1 shows user actions for taking a blood glucose reading using a first embodiment of a sensor dispensing device in accordance with the present
10 invention;

Figure 2 illustrates a mechanical sequence for dispensing a sensor from a stack of sensors in a device in accordance with embodiments of the present
15 invention;

Figure 3 shows external views of a second embodiment of a sensor dispensing device in accordance with the present invention;
20

Figures 4 and 5 show part-sectional views of the device of Figure 3;

Figure 6 is an exploded drawing of the device of Figure 3;
25

Figure 7 shows external views of a third embodiment of a sensor dispensing device in accordance with the present invention;
30

Figures 8 and 9 show part-sectional views of the device of Figure 7;

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DETAILED DESCRIPTION

In the following description the same numbers will be used to refer to equivalent parts of the various embodiments.

5

Referring to Figure 1, the sensor dispensing device 2 can be held in a user's hand. The device 2 has an external slidable sleeve 4 and a display 6, in this example an LCD. From the rest position of Figure 1a, the user pulls back
10 the actuating sleeve 4 (Figure 1b) against a spring force. As will be explained later, this action opens the cap on a stack of sensors in a housing. The user releases the sleeve 4 (Figure 1c) and the spring force returns the sleeve 4 to the rest position, in the process of which the
15 device is activated to take a reading, a sensor 8, in this example a test strip, is presented to receive a drop of blood, and the cap returns to make a seal with the housing. The user applies a sample of blood to the sensor 8 (Figure 1d) and the glucose value is shown on the LCD 6.
20 The used sensor 8 is then discarded.

Figure 2 illustrates schematically the mechanical sequence of events occurring inside the device 2. A cartridge assembly 32 comprises a cartridge outer 10 which encloses
25 a cartridge inner 70. The cartridge inner 70 is a housing which has a single opening covered by a spring-biased cap 16. In the rest position shown in Figure 2a, the cap 16 is pressed against the cartridge outer 10 to make a moisture-tight seal. In the housing 70 is a stack 12 of
30 test strips 8, urged towards the cap 16 by a sprung follower 14. A stop member (best illustrated in Figures 13 and 14) limits outward travel of the test strips 8

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of the test strip 8 engage when the strip is in the engagement location, as best shown in Figure 17.

Cartridge access from the side of the device is provided
5 by a cartridge cover 44 which is opened by operation of a release button 26. In this example the cartridge cover 44 provides access to batteries 38 in addition to the cartridge assembly 32. The batteries 38 and cartridge assembly 32 are received in a single moulded chassis 50.
10 A download socket 40 is provided for downloading external data such as calibration values for the test strips. The sleeve 4 is connected to an actuator rack 36 which is connected to a strip-pusher rack 34 via a pinion gear arrangement (not shown in Figures 3-6 - illustrated in
15 Figure 9). When the user pulls back the sleeve 4, the actuator rack 36 causes the strip-pusher rack 34 to move a greater distance because of the pinion gear-ratio. The strip-pusher rack 34 is connected to the slider 18 which operates as described with reference to Figure 2 above. A
20 return spring 48 acts to return the sleeve 4 to the rest position after it has been pulled back and released.

A third embodiment of the invention is illustrated with reference to Figures 7 to 10. In this embodiment the LCD
25 6 is side-mounted to maximise the gripping area without obscuring the screen. This arrangement facilitates holding the device with a precision pen-style grip as well as in a fist. The strip ejection point 24 is situated at an edge projection, which helps to indicate to the user
30 where the strip will emerge from. A separate battery cover 54 is provided, which has a battery contact member 52 provided on its inner surface. As illustrated in

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connected to a follower 14. The cartridge inner 70 is formed from a base member 71 and a closure member 72. Two opposed upstanding walls of the base member 71 are provided with a series of ridges 74 in which fit arms 76 of the follower 14. The ridges 74 and arms 76 are profiled to permit movement of the follower 14 in one direction only, towards the stack 12 of test strips. During assembly, the follower 14 is located near to the spring 68 to permit the stack 12 to fit in the cartridge inner 70. The closure member 72 is snap-fitted on the base member 71 to form the cartridge inner 70 which is located in the cartridge outer 10. A lip 73 on the closure member 72 provides a stop member which limits outward travel of the stack 12. There is a sufficient gap between the lip 73 and the adjacent walls of the base member 71 (which define an opening of the housing) to permit a single strip 8 to slide out axially, as illustrated with reference to Figure 2.

20 An alternative cartridge assembly design, for a replacement cartridge assembly 32, is shown in Figure 14. Here the stop member 73 is provided on the base member 71. After closing the closure member 72 (Figure 14a) the cartridge inner 70 is put in the cartridge outer 10 (Figure 14b) to form the cartridge assembly 32. An elongate channel 75 is disposed parallel to the top edge of the closure member 72, allowing access of a pushing member, from the side or the top as viewed, to push out the test strip adjacent to the stop member 73. Finally the cartridge assembly 32 is put in a foil bag 82 (Figure 14c) and sealed. The bag may be provided with a desiccant to keep the cartridge assembly 32 in a low moisture

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provided with a location pin 84 to engage in recesses in the chassis through holes 92 in the PCB 30. Contacts 90 in the second moulded member engage with electrodes on the test strip 8 and are electrically connected with the main
5 PCB 42 via a flexible connector 80.

It is appreciated that certain features of the invention, which are for clarity described in the context of separate embodiments, may also be provided in combination in a
10 single embodiment. Conversely, various features of the invention which are, for the sake of brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

15 Although the invention has been described with reference to a sensor dispensing device or test device for measuring blood glucose concentration, it is to be understood that the invention is not limited to this application. The invention may be used in the determination of any analyte
20 in a fluid, biological or otherwise, by the use of suitable reagents in the test strip. Such reagents are well known to those skilled in the art.

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said dispensed position.

3. A sensor dispensing device as claimed in claim 1 or claim 2, wherein the pushing member and the means for making or breaking the seal are actuated by operation of a single external actuating member.

4. A sensor dispensing device as claimed claim 3, wherein the actuating member is slidably mounted in relation to the housing.

5. A sensor dispensing device as claimed in any one of the preceding claims, wherein the pushing member is reciprocally slidable between a first position and a second position.

6. A sensor dispensing device as claimed in claim 5, wherein the arrangement is such that movement of the pushing member from the first position to the second position will cause the pushing member to insert at least a portion of itself between a sealing surface and the sealing member so as to break the seal and then to travel to an extent sufficient to permit a sensor to be urged to a position where it will be pushed through the gap by the pushing member in the course of its return journey to the first position.

7. A sensor dispensing device as claimed in claim 6, wherein the arrangement is such that the pushing member will push in opposite directions on both the sealing member and the nearest sensor in the stack as it travels from the first position to the second position.

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relation to the housing for engaging with the said electrode tracks at the said dispensed position; and wherein the said signal-reading means comprises a meter connected to the electrical contacts, having electronics means for producing a signal output which is dependent on the electrical signal from a sensor when the sensor is engaged with the said contacts.

14. A sensor dispensing device as claimed in any one of the preceding claims, wherein the housing is part of a removable cartridge assembly.

15. A cartridge assembly for use in a sensor dispensing device in accordance with claim 14, the cartridge assembly comprising:

- a) a housing having a plurality of sensors arranged in a stack therein, each sensor carrying reagent means for producing a signal in response to the concentration of analyte in an applied fluid;
- 20 b) the housing having an opening of sufficient dimensions to permit a sensor to pass through the opening;
- c) a stop member located beyond the opening which limits outward travel of sensors from the stack;
- d) a spring means which urges the sensors towards and into contact with the stop member;
- 25 e) a fixed gap between the stop member and the said opening of suitable dimensions to permit a sensor to be pushed through the said gap; and
- f) at least one sealing surface on or around the housing for making a moisture-tight seal with a suitable sealing member so as to protect sensors in the housing from atmospheric moisture.
- 30

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e) a fixed gap between the stop member and the said opening of suitable dimensions to permit a sensor to be pushed through the said gap;

5 wherein the opening of the housing has two opposed edges, the stop member being attached to or integrally formed with one of the said opposed edges, and spaced apart from at least a portion of the other opposed edge.

20. A sensor dispensing device or cartridge assembly as
10 claimed in any preceding claim, wherein the dimensions of the gap are such as to permit only a single sensor at a time to be pushed through the gap.

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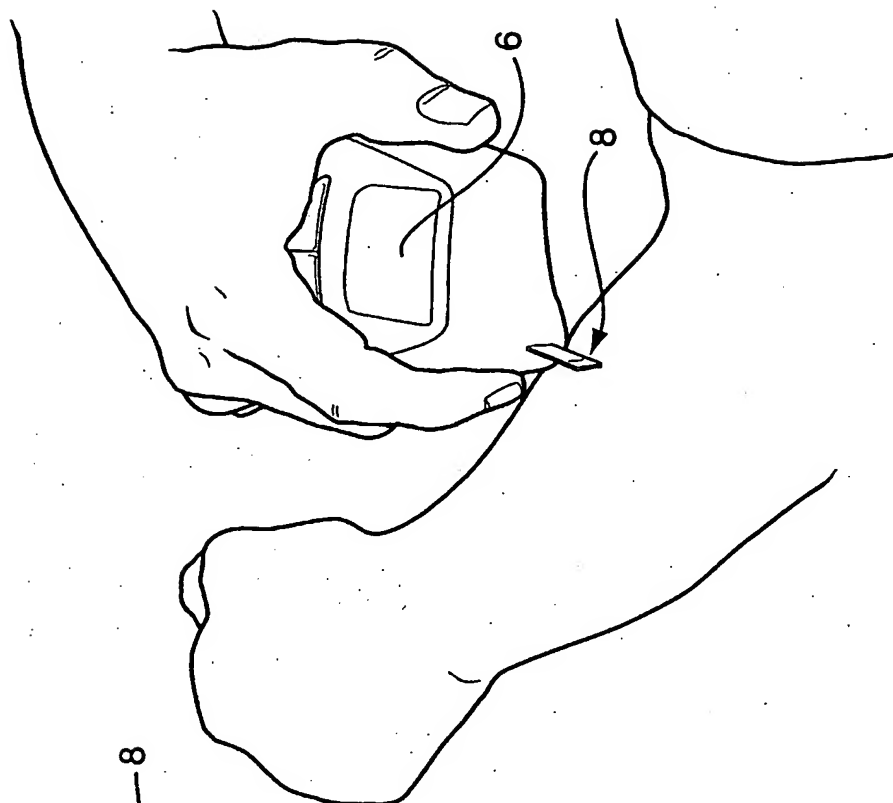


FIG. 1d

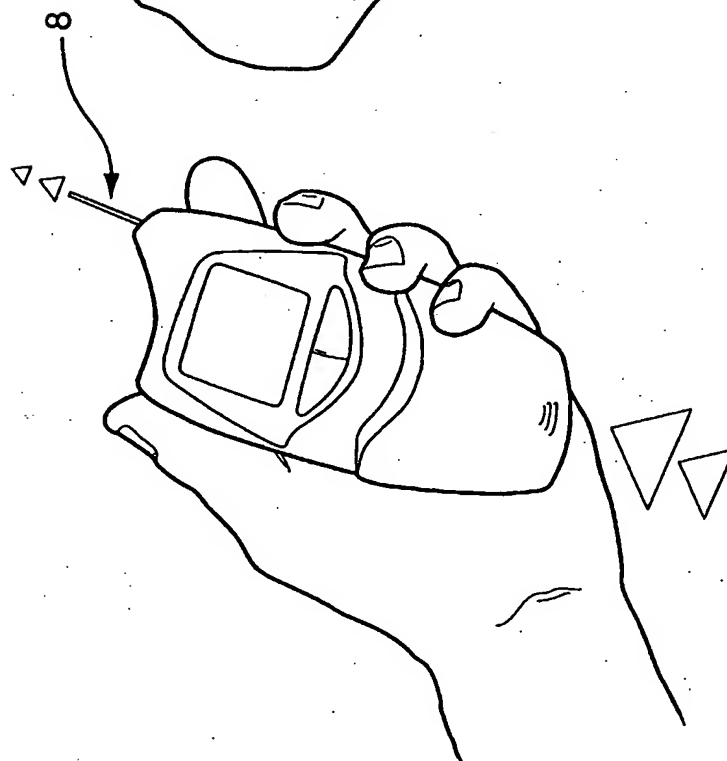


FIG. 1c

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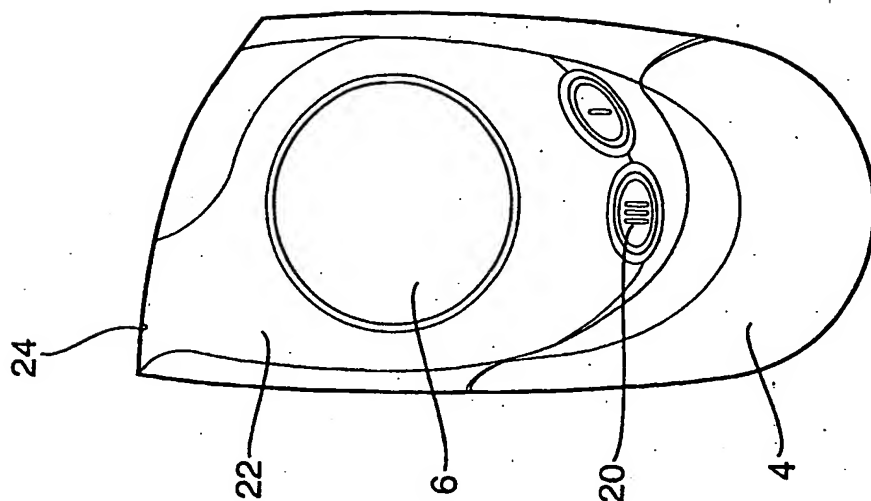


FIG. 3c

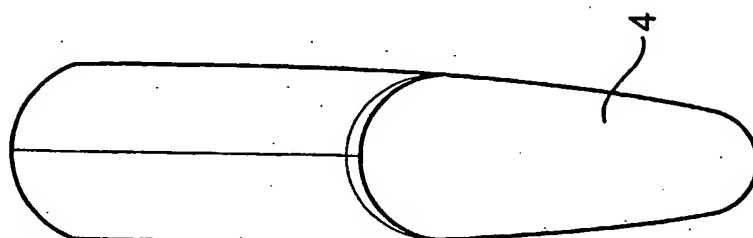


FIG. 3b

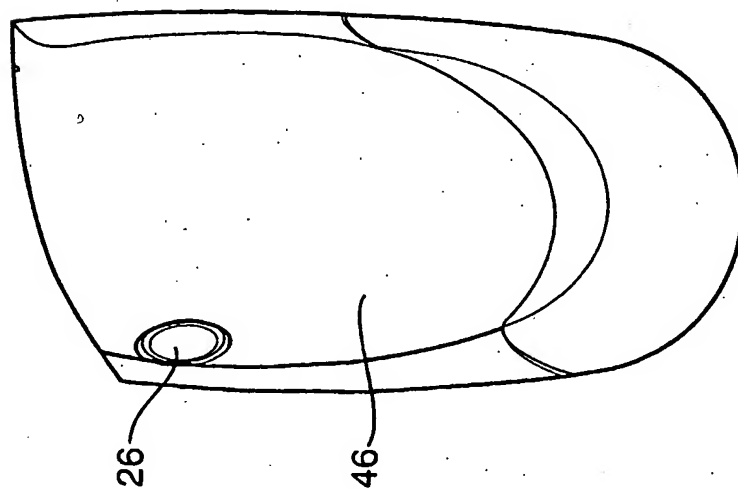


FIG. 3a

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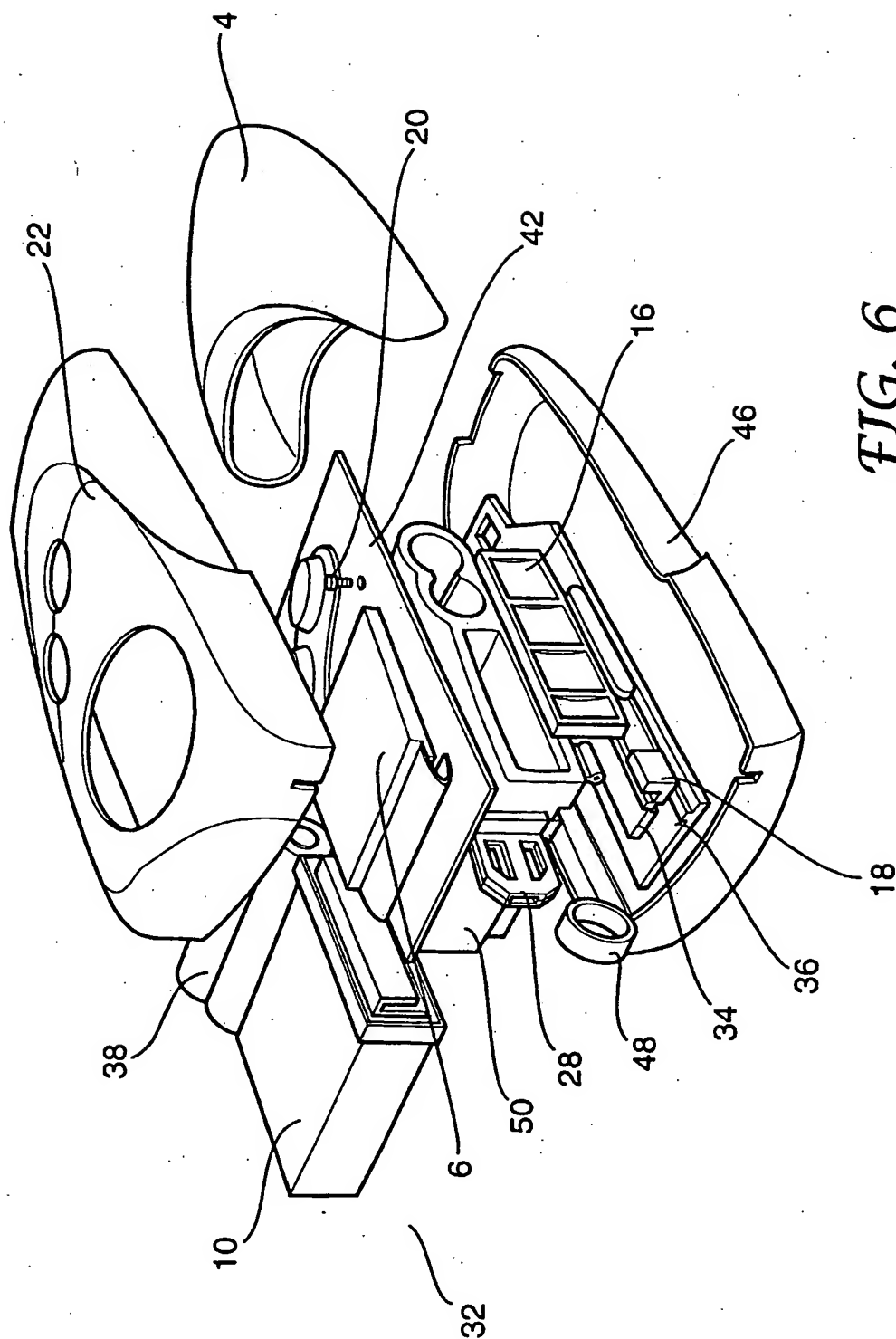
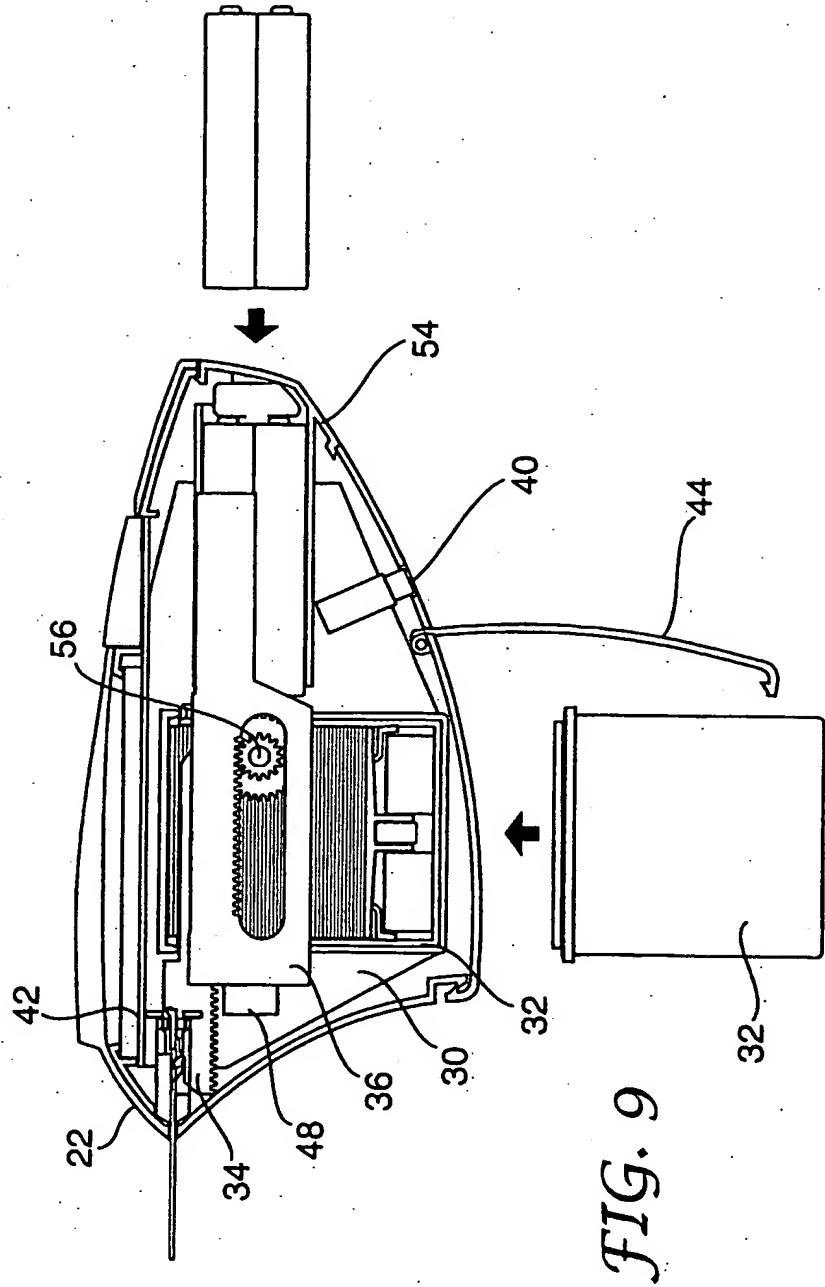
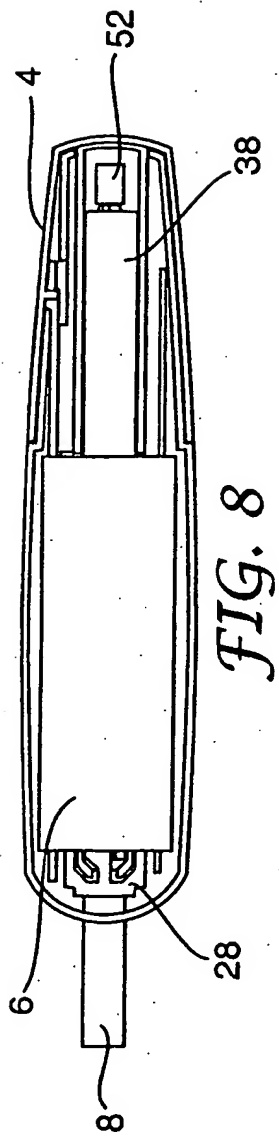


FIG. 6

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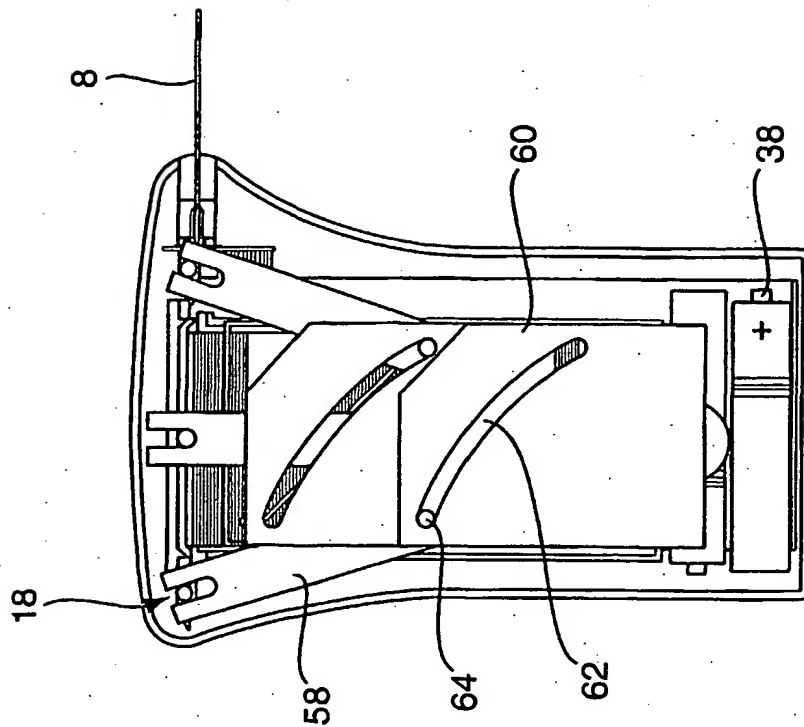


FIG. 12

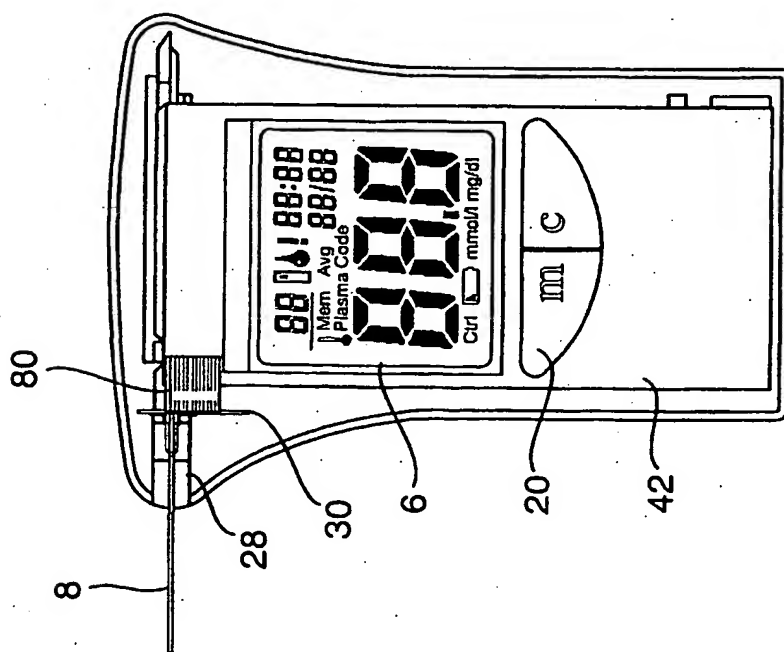


FIG. 11

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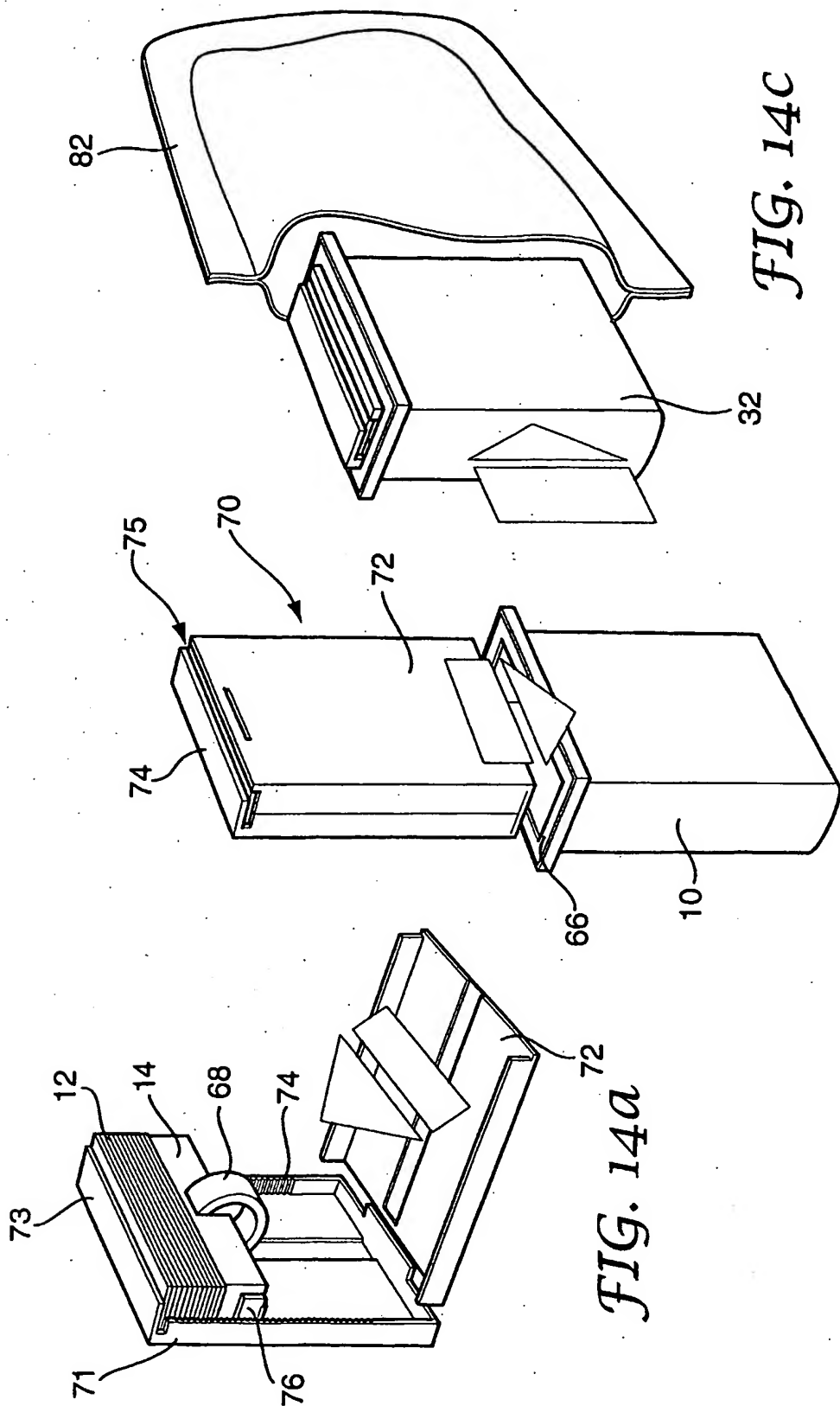
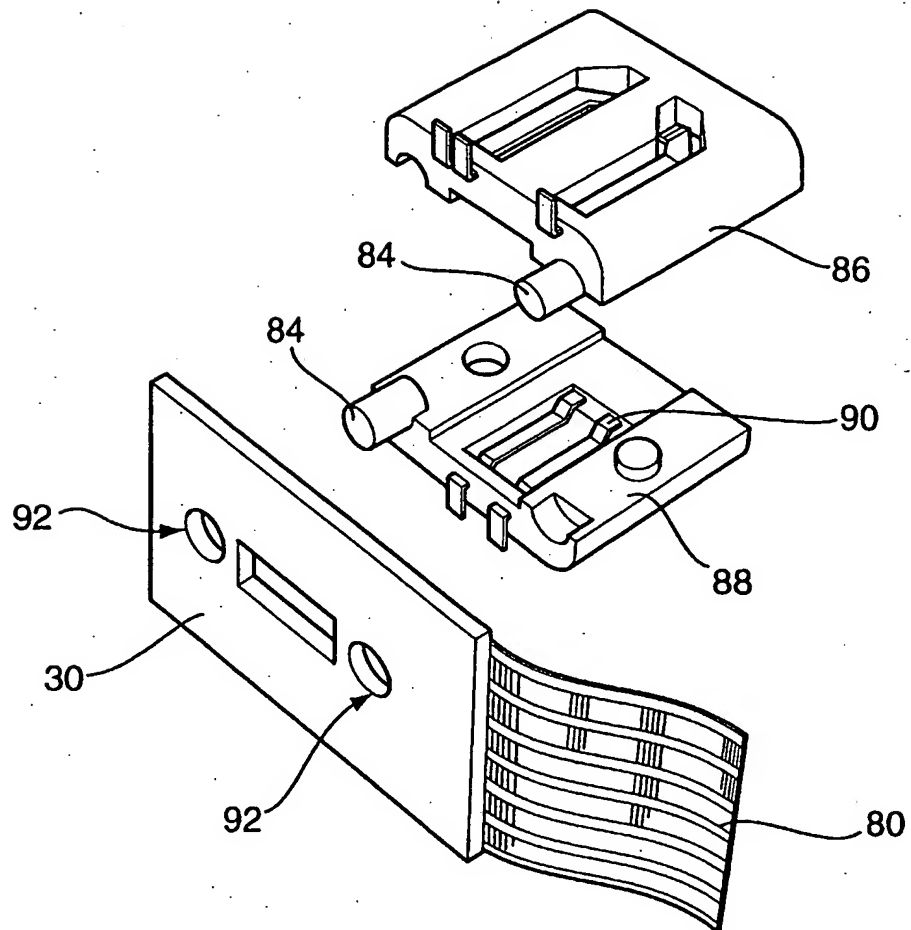


FIG. 14a

FIG. 14b

FIG. 14c

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*FIG. 17*

INTERNATIONAL SEARCH REPORT

Inte of Application No
PCT/GB 02/03739

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N33/487

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N B01L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 94 10558 A (ENVIROMED) 11 May 1994 (1994-05-11) cited in the application page 1, paragraph 3 -page 6, paragraph 2; figures --- -/--	1-9, 11, 13-16, 20 10, 12, 17-19

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 02/03739

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9410558	A	11-05-1994	AU 5374594 A EP 0667956 A1 WO 9410558 A1	24-05-1994 23-08-1995 11-05-1994
JP 62030962	A	09-02-1987	NONE	
US 5271896	A	21-12-1993	AT 167575 T DE 69411082 D1 DE 69411082 T2 EP 0627628 A2 JP 3321286 B2 JP 6324056 A	15-07-1998 23-07-1998 03-12-1998 07-12-1994 03-09-2002 25-11-1994
GB 2001443	A	31-01-1979	CA 1095285 A1 FR 2398306 A1	10-02-1981 16-02-1979
US 4142863	A	06-03-1979	DE 2965718 D1 EP 0006031 A1 JP 1353407 C JP 54160296 A JP 61018986 B US RE30595 E	28-07-1983 12-12-1979 11-12-1986 18-12-1979 15-05-1986 28-04-1981
EP 0885591	A	23-12-1998	FI 972634 A EP 0885591 A2 JP 11070098 A US 6159424 A	20-12-1998 23-12-1998 16-03-1999 12-12-2000
WO 0218940	A	07-03-2002	AU 8418601 A WO 0218940 A2 US 2002057993 A1	13-03-2002 07-03-2002 16-05-2002